

REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars.

1. In the claims

As shown in the foregoing LIST OF CURRENT CLAIMS, the claims have been amended to more clearly point out the subject matter for which protection is sought.

Claims 19-32 are amended to recite a method for inserting a punctal plug into a punctum canaliculus, where the punctal plug has the recited features, and removing and reinserting (or just removing) the punctal plug if the plug is not properly positioned, or if the plug is properly positioned, removing the fine thread from the plug. It is respectfully submitted that no new matter is added, since support for the amendments may be found, for example, at least on page 3, lines 33-34, page 4, lines 21-25 and 30-31, page 5, lines 28-29, page 9, lines 34-38, and page 11, lines 16-20 of the accompanying description in the specification as originally filed.

Entry of the LIST OF CURRENT CLAIMS is respectfully requested in the next Office communication.

2. Rejection of claims 19-30 and 32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent no. 6,290,684 (Herrick) in view of U.S. patent no. 5,171,270 (Herrick) and further in view of U.S. publication no. 2003/0125748 (Li et al.)

Reconsideration of this rejection is respectfully requested on the basis that the rejection fails to establish a *prima facie* case of obviousness with respect to amended claims 19 and 27, from which the remaining pending claims respectively depend.

By way of review, amended claims 19 and 27 recite a method of inserting a punctal plug into a punctum canaliculus, where the punctal plug includes a shaft, a tip portion, a brim, and a fine thread removably inserted into a part of the punctal plug. The fine thread is used in two manners, the first is if the punctal plug is not properly

positioned, then the punctal plug is pulled out by pulling both ends of the fine thread, and the plug can then be reinserted, and the second is if the punctal plug is properly positioned, then the fine thread is pulled out of the punctal plug by pulling one end of the fine thread.

Thus, if the plug is not properly positioned, for example, if the plug is accidentally inserted too deeply into a canaliculus, then the plug can be pulled out by pulling both ends of the fine thread so as to remove the plug from the improper position, and the plug can then be reinserted into the canaliculus.

However, if the plug is properly positioned, then the fine thread is removed from the plug, while the plug remains in place in the proper position. This is accomplished by pulling on one end of the thread, such that the thread is removed from the punctal plug, while the plug remains in position. In other words, the plug itself is not removed, but instead, is maintained in the proper position, while the thread is removed from the plug. If it is desired to remove the punctal plug after the thread has been removed from the plug, the plug can be removed by grasping the brim of the plug with a pair of tweezers, for example. It may be desired to remove the plug in this manner if some problem, like epiphora, takes place.

It is respectfully submitted that the proposed combination of the *Herrick* '684, and the *Herrick* '270 patents, with the *Li* publication fails to disclose at least a fine thread used in the above-stated two manners, first if the punctal plug is not properly positioned, then the punctal plug is pulled out by pulling both ends of the fine thread, second if the punctal plug is properly positioned, then the fine thread is pulled out of the punctal plug by pulling one end of the fine thread, as is required by the methods recited in amended claims 19 and 27.

The *Herrick* '684 patent discloses a punctum plug 178 having an elongated member 180 having a central axis and a pair of spaced ends 184 and 186 (col. 12, lines 9-13).

As acknowledged in the Office action on page 3, the *Herrick* '684 patent fails to disclose a fine thread.

The Office action next turns to the *Herrick* '270 patent, which discloses a canalicular implant 20 having an elongated central member 22 with a pair of ends 26, 34 (col. 6, lines 55-61). One of the ends is a collapsible flared end 36 having an outer ring 40 (col. 6, lines 60-61; col. 7, lines 1-4).

An elongated, thread-like member 44, a cord or a long slender flexible material, can be attached to the outer ring 40 of the collapsible flared section 36 and be of sufficient length to extend from the canalicular implant, located within the horizontal portion of the canaliculus, to the punctum such that an eye surgeon can apply a pulling force on the thread-like member to retrograde and remove the canalicular implant (col. 5, lines 11-20; col. 7, lines 19-36).

In other words, the thread-like member 44 has a single end which is pulled by an eye surgeon in order to remove the canalicular implant, which is in contrast to amended claims 19 and 27, which require 1) that both ends of the fine thread are pulled to remove the plug if the plug is not properly positioned, and the plug can be reinserted (claim 19), and 2) that once the plug is properly positioned, the fine thread is removed from the punctal plug by pulling one end of the thread.

Further, the *Herrick* '270 patent fails to disclose or suggest that the thread-like member 44 is removable from the canalicular implant.

After the canalicular implant 20 of the *Herrick* '270 patent is properly positioned in the horizontal portion of the canaliculus, if the thread-like member is too long, then a part of the thread-like member, which extends over the punctum, should be cut so as to avoid irritation of the patient's eye. Thus, in a usual case, the thread-like member is arranged in such a way that the thread-like member does not extend out of the punctum. For this reason, it is difficult to pull out and remove the canalicular implant after it is properly positioned, even if such a short-cut thread-like member is attached to the

canalicular implant. Further, the upper end of the thread-like member may move deeply so as to move far from the punctum, which can sometimes result in epiphora. In such a case, dacryocystorhinostomy or the like may be required.

With regard to various problems associated with the use of the lacrimal plugs described in the *Herrick* '684, and the *Herrick* '270 patents, a number of research articles are cited in the concurrently filed IDS, in which such problems are discussed.

With regard to the thread-like member 44 of the *Herrick* '270 patent, the Office action acknowledges on page 4 that the thread-like member 44 of the *Herrick* '270 patent does not have two free ends.

Accordingly, since the thread-like member 44 of the *Herrick* '270 patent fails to disclose two free ends, it follows that the *Herrick* '270 patent fails to disclose pulling on both free ends in order to remove the lacrimal plug of the *Herrick* '270 patent.

The Office action turns to the *Li* publication as disclosing an implant attached to an implant delivery device by a suture loop. The Office action asserts on pages 4-5 that the suture loop 160 has two opposing ends passing through an aperture 162 extending through the implant 102 so as to allow the implant to be retracted towards the delivery device 170 (by pulling on opposing ends of the suture loop).

However, by definition, a loop does not have ends, and thus, the suture loop of the *Li* publication does not have two ends, as is required by the fine thread of amended claims 19 and 27.

Thus, the *Li* publication fails to disclose the method recited in amended claims 19 and 27 of pulling both ends of the fine thread to remove the plug if the plug is not properly positioned.

Accordingly, even if the suture loop of the *Li* publication were added to the plug of the *Herrick* '270 patent in place of the thread-like member 44, the proposed combination of the *Herrick* '684, and the *Herrick* '270 patents, with the *Li* publication

fails to disclose at least a fine thread used in the two recited manners, first if the punctal plug is not properly positioned, then the punctal plug is pulled out by pulling both ends of the fine thread, second if the punctal plug is properly positioned, then the fine thread is pulled out of the punctal plug by pulling one end of the fine thread, as is required by the methods recited in amended claims 19 and 27.

Accordingly, a *prima facie* case of obviousness cannot be established with respect to amended claims 19 and 27, from which the remaining pending claims respectively depend, and withdrawal of this rejection is respectfully requested.

2. Rejection of claim 31 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent no. 6,290,684 (Herrick) in view of U.S. patent no. 5,171,270 (Herrick) and U.S. publication no. 2003/0125748 (Li et al.) and further in view of U.S. patent no. 6,168,623 (Fogarty et al.)

Reconsideration of this rejection is respectfully requested, in view of the amendment to claim 27, from which claim 31 depends, on the basis that the *Fogarty* patent fails to provide for the shortcomings of the *Herrick* '684 patent, the *Herrick* '270 patent, and the *Li* publication, as discussed above in detail with respect to amended claim 31.

Accordingly, withdrawal of this rejection is respectfully requested.

3. Conclusion

As a result of the amendment to the claims, and further in view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is respectfully requested that every pending claim in the present application be allowed and the application be passed to issue.

Please charge any additional fees required or credit any overpayments in connection with this paper to Deposit Account No. 02-0200.

If any issues remain that may be resolved by a telephone or facsimile communication with the applicants' attorney, the examiner is invited to contact the undersigned at the numbers shown below.

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